Original Article

A randomized clinical trial to evaluate the plaque removal efficacy of an oscillating-rotating toothbrush versus a sonic toothbrush in orthodontic patients using digital imaging analysis of the anterior dentition

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ABSTRACT

Objective: To compare the plaque removal efficacy of an oscillating-rotating electric toothbrush with an orthodontic brush head versus a sonic toothbrush in adolescent patients with fixed orthodontic appliances.

Materials and Methods: This was a randomized, examiner-blind, replicate single-use, two-treatment, four-period, crossover study with a washout period between visits of approximately 24 hours. Forty-four adolescent patients with fixed orthodontic appliances in both arches were randomized based on a computer-generated randomization schedule to one of four toothbrush treatment sequences. The primary outcome was plaque score change from baseline, measured using digital plaque imaging analysis.

Results: Baseline plaque levels for both brush treatments were high, covering more than 50% of the tooth area. Effective plaque removal was observed with both brush treatments ($P < .001$); however, the reduction in plaque with the oscillating-rotating toothbrush was statistically significantly greater ($P = .017$) compared with the sonic toothbrush.

Conclusions: The study provides evidence for more effective plaque-removing efficacy of the oscillating-rotating toothbrush versus the sonic toothbrush among orthodontic patients. (*Angle Orthod.* 2019;89:385–390.)

KEY WORDS: Oral hygiene; Orthodontic; Plaque removal; Power toothbrushes

INTRODUCTION

Thorough daily oral hygiene is necessary for the maintenance of oral health and is especially challenging for patients with fixed orthodontic appliances. Plaque trapped around fixed orthodontic appliances increases the risk of dental caries and the development of demineralization around orthodontic brackets ("white spots").[1–4] Increases in periodontal pathogens and the incidence of gingivitis have also been observed in patients wearing fixed orthodontic appliances.[5–7] Other factors affecting oral hygiene during treatment include discomfort associated with orthodontic-related gingivitis and the fact that most orthodontic care occurs in adolescents aged 9 to 14 years, an age when noncompliance is common.[8,9]

Oral hygiene product manufacturers have incorporated special design features for plaque removal around fixed orthodontic appliances. For example, oscillating-rotating electric toothbrushes, which rotate in a clockwise-counterclockwise motion, can be combined with a specialized orthodontic brush head

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configured to reach around the brackets and other components of orthodontic appliances. Data for non-orthodontic patients confirmed that oscillating-rotating toothbrushes are more effective at removing plaque and reducing gingivitis than manual brushes.[10–12] The oscillating-rotating toothbrush technology has also demonstrated advantages over sonic toothbrushes, which move laterally in a side-to-side motion.[13–20]

Measuring plaque removal in orthodontic patients requires a methodology that takes into account uneven plaque distribution around components of orthodontic appliances. Digital plaque image analysis (DPIA) is an objective, sensitive means of assessing plaque levels that has been successfully applied in orthodontic patients.[21,22] Using DPIA methodology in a single-use comparative plaque removal clinical study among orthodontic patients, greater efficacy of an oscillating-rotating toothbrush over a manual toothbrush has already been demonstrated, together with the advantage of an orthodontic brush head over a regular brush head.[23] The study on orthodontic patients reported in this article used a similar methodology and study design to compare the plaque removal efficacy of an advanced oscillating-rotating brush fitted with an orthodontic brush head versus a leading sonic toothbrush.

MATERIALS AND METHODS

This study was carried out in Mainz, Germany. All subjects were patients from the Department of Orthodontics at the University Medical Center of the Johannes Gutenberg–University of Mainz. Prior to beginning the study, the protocol was approved by the Freiburger Ethik–Kommission International (feci code 09/1616), and each subject, as well as the subject's guardian, gave signed informed consent.

Subjects were screened before study entry, and their medical and dental history were reviewed. To participate, subjects were required to be at least 12 years of age, in good general health, have fixed orthodontic appliances on both arches, and have at least eight natural anterior teeth with facial scorable surfaces. Subjects were instructed not to use non-study oral care products during the study, other than their usual toothbrush and a regular fluoridated dentifrice during the 24-hour washout period between each visit. In addition, subjects were required to agree to abstain from performing any oral hygiene procedures after their evening brushing (not later than 11 PM) prior to the day of their scheduled study visit and to abstain from eating, drinking (except sips of water), smoking, and chewing gum for 4 hours before a study visit. Subjects could not participate in any other dental

Figure 1. (a) Sonic brush (left). (b) Oscillating-rotating brush (right).

clinical study nor receive any elective dental treatment, including dental prophylaxis, until study completion.

The oscillating-rotating electric toothbrush with orthodontic brush head (Oral-B Triumph, D27/OD17, Procter & Gamble, Cincinnati, Ohio) was compared with the sonic toothbrush (Sonicare FlexCare with ProResults brush head, HX6011, Philips Oral Healthcare Inc, Bothell, Wash; see Figure 1).

A randomized, replicate single-use, two-treatment, four-period, crossover, examiner-blind study design was used. There were four different treatment sequences, determined by a computer-generated randomization plan prepared before the study: AABB, BBAA, ABBA, and BAAB, where A and B represented the two different brush treatments. The sequence determined the order in which the brushes were assigned to subjects for the four treatment visits, and equal numbers of subjects were randomized to each sequence. There were washout periods of approximately 24 hours between visits. Kits containing treatment products were assigned by site staff outside the view of the investigator (Dr Erbe) to ensure blinding. The study sponsor and all study personnel, except those involved in product distribution, were blinded to treatment until the study concluded and the database was finalized and locked.

At the first (screening/acclimation) visit, subjects disclosed their plaque with fluorescein by rinsing for 10 seconds with 25 mL of phosphate buffer, rinsing for 1 minute with 5.0 mL of 1240 ppm fluorescein in phosphate buffer, then rinsing three times for 10 seconds with 25 mL of phosphate buffer. Plaque levels of the facial surfaces of subjects' anterior teeth (13–23 and 33–43) were assessed using DPIA, developed by Sagel et al.[21] and as described by Erbe et al.[22]; subjects who qualified according to the inclusion and exclusion criteria were supplied with the study treatment brushes and marketed dentifrice (Blendax Antibelag, Gross Gerau, Germany) in an acclimation kit. At this visit, subjects were given brushing instructions (per the manufacturer's usage instructions), and they used each brush for 1 minute under supervision.

Subjects used their acclimation products at home in place of their usual toothbrush product for regular brushing (2 minutes for each brushing, alternating the brushes morning and evening) for approximately 4 days. Subjects switched back to their usual toothbrush but continued with the acclimation toothpaste 48 hours prior to the start of period 1 (visit 2) and continued using their usual toothbrush and acclimation toothpaste in between treatment visits. At visit 2, subjects' plaque was disclosed as described above, and a prebrush DPIA image was taken. Subjects were randomized to one of four treatment sequences and instructed to brush for 2 minutes, according to the manufacturer's instructions, with their assigned brush for that treatment period and the marketed toothpaste. Brushing was monitored by a site staff member and was unaided by a mirror. Following brushing, subjects redisclosed their plaque with fluorescein, as described for the first visit, and a postbrushing DPIA image was taken. The next treatment visit was scheduled, and subjects were reminded to use their usual toothbrush and the acclimation toothpaste in between treatment visits. Also, subjects were reminded to perform their last oral hygiene in the evening, no later than 11 PM, before each scheduled treatment visit day and to refrain from eating, drinking (except sips of water), chewing gum, or smoking for 4 hours before their afternoon appointment time. The procedures for periods 2–4 (visits 3–5) were the same as for period 1; see Figure 2.

Subjects received an oral soft tissue examination before and after brushing at each treatment visit.

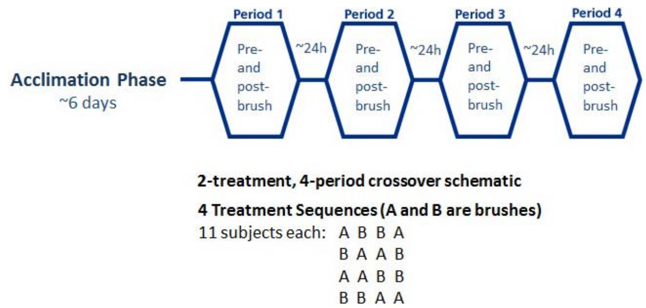

Figure 2. Study diagram.

Statistical Analyses

Prestudy sizing was achieved using power analyses with $\alpha = .05$, using a two-sided test and a sample size of 44. This sample size was computed using variability (SD = 6.2) and treatment difference (2.7%) estimates from previous research of similar crossover design to ensure enough subjects to separate the treatments statistically.

The data were analyzed using SAS software (SAS Institute Inc., Cary, NC, USA); treatment comparisons were two-sided and carried out at a significance level of .05. Plaque was measured, using DPIA, as the percentage of tooth area covered, and these values were averaged to give a single DPIA score prebrushing (baseline) and a single score postbrushing for each subject, for each of the four treatment periods. The differences between baseline and postbrushing scores were computed for each subject and on each treatment visit. A mixed-model analysis of covariance for a crossover design was used to assess the treatment difference with terms in the model for subjects (random effect), treatment, period, and carryover and the average baseline plaque percentage as the covariate. The carryover term was found to be nonsignificant ($P > .1$); therefore, the final crossover model did not include this term. In addition, for each treatment, a *t*-test was conducted on the adjusted treatment mean score differences from the analysis of covariance to analyze the adjusted mean plaque removal scores for statistical significance from zero. The *t*-test was carried out for each treatment separately using the adjusted treatment differences (prebrushing minus postbrushing) to assess whether the plaque differences were statistically different from zero, which was analogous to testing whether the postbrushing plaque percentages were different from their prebrushing plaque percentages.

RESULTS

Forty-four subjects between 12 and 25 years of age (mean age 14.7 years, standard deviation 2.48) were randomized to one of the four treatment sequences (11

Table 1. Baseline Demographics

	Mean	Min-Max	SD
Age, y	14.7	12–25	2.48
	Frequency	Percentage	
Gender			
Female	17	38.6	
Male	27	61.4	
Race			
Caucasian	42	95.4	
Asian Oriental	1	2.3	
Asian Indian	1	2.3	

subjects per sequence). Baseline demographics can be found in Table 1.

The average baseline (prebrushing) plaque percentage scores, mean plaque reductions (baseline minus postbaseline), and mean postbrushing plaque percentage scores for each treatment are shown in Table 2. Baseline plaque scores were >50% for each treatment and did not differ significantly between groups ($P =$ .984). Both treatments revealed statistically significant postbaseline plaque reductions ($P <$ .001). The plaque reduction from baseline was 60.76% for the sonic toothbrush with a standard brush head and 65.62% for the oscillating-rotating toothbrush with an orthodontic brush head (Table 2). Treatment effect tests found the oscillating-rotating toothbrush provided statistically significantly greater plaque reduction than the sonic toothbrush ($P =$ .017).

Pre- and postbrushing DPIA image examples for a single patient using each toothbrush are shown in Figure 3. No adverse events were reported.

DISCUSSION

Nearly 6 million people in the United States have been reported to receive orthodontic treatment in a given year.[23,24] In addition, treatment duration with fixed orthodontic appliances is typically 2 to 3 years. Considering the length of treatment and the number of patients receiving treatment, it is important that toothbrush manufacturers and dental professionals continue to provide specialized products for plaque removal.

Compared with manual brushes, electric brushes have demonstrated plaque removal advantages over their manual counterparts, both among general and orthodontic populations.[22,25–27] In a replicate use, single-brushing trial with 45 adolescent and young adult orthodontic subjects,[22] an oscillating-rotating toothbrush, both with an orthodontic brush head and a regular brush head, showed statistically significant plaque removal advantages over a standard manual toothbrush.

Oscillating-rotating toothbrush technology has also shown advantages over other electric toothbrush technologies. Several studies, including a systematic review comparing electric toothbrush technologies to each other, have shown oscillating-rotating brushes reduce plaque and gingivitis more effectively than those with a side-to-side action (sonic) in the short term (4–12 weeks) among nonorthodontic patients.[13–19] Research has also shown patient preferences for the oscillating-rotating technology versus sonic.[17] The present plaque removal trial was conducted specifically among orthodontic subjects to compare the oscillating-rotating/orthodontic brush head combination with the sonic brush/standard brush head combination using an established design and plaque evaluation method.[13,21,22,25] The results showed that baseline plaque levels for both brush treatments were high (>50% of the tooth area) and that both brushes were effective at removing plaque on single use. The oscillating-rotating/orthodontic brush head combination demonstrated statistically significant superiority over the sonic/standard brush head combination ($P =$ .017). While the clinical significance of these findings is subjective, decades of research indicate that oscillating-rotating electric toothbrushes should be the first-line recommendation for daily mechanical hygiene.[10–20]

The use of DPIA, specifically measuring plaque only on the facial surfaces of anterior teeth, and the short study duration with single-use brushing episodes could be considered potential limitations of the trial. Howev-

Table 2. Summary of Pre- and Postbrushing Plaque Assessment

Toothbrush	Mean Prebrushing Plaque	Adjusted Mean Reduction (Standard Error)	Mean Postbrushing Plaque[a]	% Reduction From Baseline[b]	Differences Between Toothbrushes: % Difference[c]	Differences Between Toothbrushes: Significance[d]
Oscillating-rotating brush group (n = 44)	51.25%	33.63% (1.22)	16.62%	65.62%		
Sonic brush group (n = 44)	51.22%	31.12% (1.22)	20.10%	60.76%	2.51%	$P =$ .017

[a] Postbrushing mean = prebrushing mean plaque – adjusted mean plaque reduction.
[b] Reduction between the pre- and postbrushing plaque scores, expressed as a percentage of the prebrushing score.
[c] Difference between pre- and postbrushing reductions in plaque.
[d] Carryover effect was not significant ($P =$ .296) and was removed from the model. The final model included prebrushing plaque, period, and treatment as fixed effects and subject as random effect and used compound symmetry covariance structure.

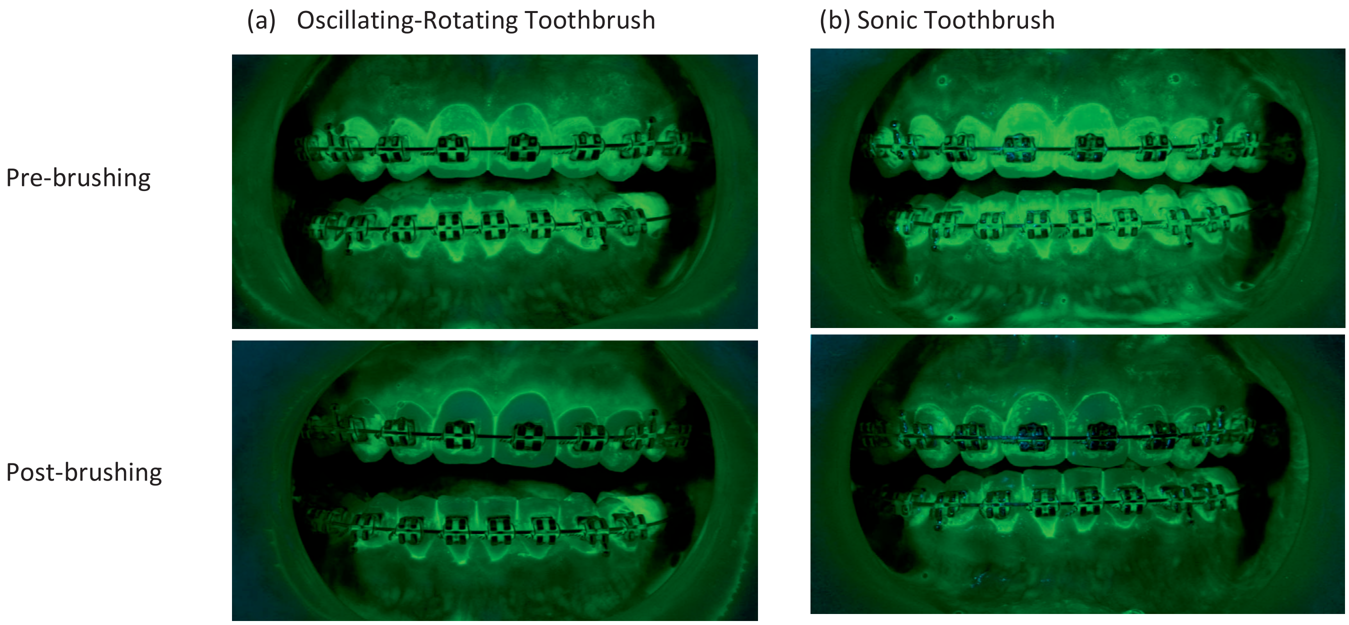

Figure 3. DPIA images of the same patient pre- and postbrushing with (a) oscillating-rotating toothbrush with orthodontic brush head and (b) sonic toothbrush with standard brush head.

er, traditional plaque indices are not designed to measure irregular plaque deposits around orthodontic brackets and are subjective.[28–31] In contrast, DPIA permits an accurate, objective, and sensitive measurement of plaque levels and has been successfully used with orthodontic patients.[20,22] Furthermore, the correlation between partial-mouth grading and whole-mouth grading has been shown to be comparable with respect to the Turesky Modified Quigley-Hein index.[32]

Regarding the study's short duration, although long-term clinical trials are preferable, they present challenges by virtue of their length. The single-use randomized crossover design is often used in comparative clinical studies to assess plaque removal efficacy of different brushes (manual and electric) and different brush heads, and results from such studies provide an indication of their relative efficacy in the long term.[33–35] Short-term studies have been conducted in nonorthodontic patients, demonstrating significant plaque reductions that were able to be extrapolated to longer-term results.[33–35] A replicate single-use design was employed, wherein both products were used twice, to further improve statistical power.

CONCLUSIONS

- An oscillating-rotating electric toothbrush with a specialized orthodontic brush head was more effective in removing plaque than a sonic toothbrush with a standard brush head in adolescent subjects with fixed orthodontic appliances.

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